

Notice of Allowability

Application No.

10/025,237

Examiner

Preeti Kumar

Applicant(s)

CHAPPLE ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 9/22/2005.
2. ☒ The allowed claim(s) is/are 1,2, 5, 6, 11-16 renumbered 1-10.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date See attached.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

DETAILED ACTION

Response to Arguments

1. The rejection of claims 1-2 and 4-16 under 35 U.S.C. 103(a) as being unpatentable over Hauwermeiren et al. (WO 98/06811) is withdrawn in light of Applicants arguments and upon entry of the Examiner's Amendment below.

EXAMINER'S AMENDMENT

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee. Authorization for this examiner's amendment was given in a telephone interview with Rimma Mitelman on Aug. 3, 2006. Support for the amendment can be found in the original claims and example 1.

3. The application has been amended as follows:

The claims:

In claim 1, line 1, delete "Antibody granule consisting essentially of:

(a) one or more antibodies, or fragments derived thereof,

(b) granulated with an alkali metal salt,

wherein the granule consists of more than 80% of the alkali metal salt." and replace with – A process for preparing an antibody granule consisting essentially of

granulating one or more antibodies, or fragments derived thereof, with a solid alkali metal salt, and an acrylate/maleate copolymer binder, wherein the antibody granule contains more than 80 wt.% alkali metal salt.--.

In claim 2, line 1, delete "Antibody granule" and replace with --The process--.

In claim 5, line 1, delete "Antibody granule" and replace with --The process--.

In claim 6, line 1, delete "Antibody granule according to claim 1, wherein the chemical equilibrium constant K_d for the antigen is" and replace with --The process according to claim 1, wherein the antibody has a chemical equilibrium constant K_d for its antigen of --.

In claim 11, line 1, delete "Process according to claim 10, whereby the temperature is of 30°C or higher." and replace with -- The process according to claim 1, where in the granulating temperature is 30°C or higher.--.

In claim 12, line 1, delete "Process according to claim 10, whereby the pH is kept at a value from 6.0 to 10.0." and replace with --The process according to claim 1, wherein the granulating pH is kept at a value from 6.0 to 10.0.--.

In claim 13, line 1, delete "Antibody granule according to claim 1, wherein the granule consists for more than 90% of the alkali metal salt." and replace with -- The process according to claim 1, wherein the antibody granule contains more than 90 wt.% alkali metal salt.--.

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In claim 14, line 1, delete "Antibody granule" and replace with –The process--.

In claim 15, line 1, delete "Process according to claim 10, whereby the temperature" and replace with – Process according to claim 1, wherein the granulating temperature--.

In claim 16, line 1, delete "Process according to claim 10, whereby the pH" and replace with – Process according to claim 1, wherein the granulating pH--.

Claims 4, 7, 8, 9, and 10 are cancelled.

Reasons For Allowance

4. The following is an examiner's statement of reasons for allowance: Claims 1,2, 5, 6, 11-16 renumbered 1-10, are allowable upon consideration of applicants' information disclosure statement and consideration of the prior art.

The prior art most pertinent to the instant claims is Hauwermeiren et al. (WO 98/06811) and Hechemy (US 4,397,959). Hauwermeiren et al. teach solid detergent compositions comprising antibody however, do not teach or suggest the claimed antibody granule having more than 80% alkali metal salt granulated with the antibody to form the antibody granule. Hechemy teach an antigen/antibody particle formed by precipitating with aqueous solutions of methanol or ethanol together with water soluble alkali metal salts such as sodium or potassium salts, said mixture containing 0.2 to 0.7% salts, however do not teach or suggest the claimed antibody granule consisting

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essentially of one or more antibodies granulated with a solid alkali metal salt and wherein in the antibody granule has more than 80% alkali metal salt.

It would not have been obvious to one of ordinary skill in the art to arrive at the specified process for preparing an antibody granule as recited by the instant claims because the prior art of record teach salting out an antibody precipitate with an aqueous solution of alcohol and 0.2 to 0.7% alkali metal salts.

None of the prior art of record teach or suggest the claimed process for preparing an antibody granule consisting essentially of one or more antibodies granulated with a solid alkali metal salt wherein said antibody granule has more than 80% alkali metal salt as recited by the instant claims.

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Preeti Kumar whose telephone number is 571-272-1320. The examiner can normally be reached on M-F 9:00am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Douglas Mc Ginty can be reached on 571-272-1029. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


DOUGLAS MCGINTY
SUPERVISORY PATENT EXAMINER

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Preeti Kumar
Examiner
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